K120291 Page 1 of 2

APR 16 2012

510(k) Summary

NAME OF FIRM:	OrthoPediatrics, Corp. 2850 Frontier Drive Warsaw, IN 46582
DATE PREPARED:	January 24, 2012
510(K) CONTACT:	Mark Fox Vice President, Regulatory Affairs Tel: (574) 268-6379
PROPOSED TRADE NAME:	OP Spine System
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3070 and 21 CFR 888.3050
CLASSIFICATION NAME:	Pedicle screw spinal system (bone screws, rods, and hooks); adolescent idiopathic scoliosis orthosis; spinal interlaminal fixation orthosis
PRODUCT CODE:	OSH; KWP
DEVICE DESCRIPTION:	The OP Spine System consists of longitudinal members (rods), anchors (hooks and screws), interconnection components (rod-to-rod and anchor-to-rod connectors) and fasteners in a variety of sizes to accommodate differing anatomic requirements.
INDICATIONS FOR USE:	The OP Spine System is intended for posterior, non-cervical fixation (pedicle screw fixation T1-S2/ilium and hook fixation (T1-L5) in pediatric patients is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and/or allograft.
MATERIALS:	Medical grade titanium alloy Medical grade cobalt-chromium-molybdenum
PREDICATE DEVICES:	Medtronic CD Horizon (K091445) Synthes USS Spinal System (K994121, K082572) Biomet Synergy VLS (K011437, K081952) DePuy Spine Isola (K980485, K022285) U&I Optima (K051971, K031585, K024096) DePuy Spine Moss Miami (K030383, K022623, K011182, K982511)

TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, and general design, and sizes of the device are the same as, or similar to, the predicate devices.
PERFORMANCE DATA:	Static and dynamic compression bending tests and static torsion tests, performed according to ASTM F1717, demonstrated that the device performs as well as or better than the predicate devices. Published clinical results for similar devices supported the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

OrthoPediatrics, Corp.
% Mr. Mark Fox
Vice President, Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K120291
Trade/Device Name: OrthoPediatrics (OP) Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: OSH, KWP
Dated: January 25, 2012
Received: January 31, 2012

Dear Mr. Fox:

This letter corrects our substantially equivalent letter of April 16, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120291

Device Name: **OrthoPediatrics' (OP) Spine System**

Indications for Use:

The OP Spine System is intended for posterior, non-cervical fixation (pedicle screw fixation T1-S2/ilium and hook fixation (T1-L5)) in pediatric patients is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and/or allograft.

Prescription Use ____X____ or Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120291